

Remarks/Argument

Applicant have received and carefully reviewed the Office Action mailed on November 22, 2010. Claims 43, 44, 46, 49, 52, and 64 have been rejected. With this Amendment, claims 61 and 64 have been amended, claims 55 and 57-58 have been canceled without prejudice, and newly presented claims 65-73 have been added. Claims 43, 44, 46, 49, 52, and 59-73 remain pending. Favorable consideration of the following remarks is respectfully requested.

Claim Rejections - 35 U.S.C. § 103

On page 2 of the Office Action, claims 43, 44, 46, and 49 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Wittenberger et al. (U.S. Patent No. 6,575,933) in view of Danek et al. (U.S. Publication No. 2002/0091379). Applicant respectfully traverses the rejection.

Turning to claim 43, which recites:

43. (Previously Presented) A device for minimally invasive medical treatment in a body of a patient, comprising:
- a tubular member having a proximal end and a distal end;
 - a cryo therapy apparatus connected to the distal end of the tubular member, wherein the cryo therapy apparatus comprises a first balloon and a second balloon, the first and second balloons arranged to define an inner chamber and an outer chamber, at least a portion of the inner chamber being interior of the first balloon and at least a portion of the outer chamber being interior of the second balloon and exterior of the first balloon, a surface of the first balloon configured to retain a coolant within the inner chamber and a surface of the second balloon configured to retain the coolant within the cryo therapy apparatus if the first balloon fails; and
 - an optical sensor disposed within the cryo therapy apparatus for monitoring temperatures created by use of the cryo therapy apparatus from within the cryo therapy apparatus, the optical sensor coupled to a retractable member capable of moving independently of the cryo therapy apparatus;
- wherein the cryo therapy apparatus is sized and arranged for vascular introduction.

Nothing in Wittenberger et al. or Danek et al., taken either alone or in combination, appear to disclose many elements of claim 43, including for example, “an optical sensor disposed

within the cryo therapy apparatus for monitoring temperatures created by use of the cryo therapy apparatus from within the cryo therapy apparatus, the optical sensor coupled to a retractable member capable of moving independently of the cryo therapy apparatus”.

In the Final Office Action, the Examiner appears to indicate that Wittenberger et al. fails to disclose the claimed optical sensor, but turns to Danek et al. for support. In particular, the Examiner cites to paragraph 37 of Danek et al. and states “Danek et al. disclose a catheter with an on-board optical temperature sensor which meets all of the limitations not disclosed by Wittenberger et al.” Applicants respectfully disagree. The cited passages of Danek et al. states:

[0037] The energy delivery device may further comprise a temperature detecting element. Examples of temperature detecting elements include thermocouples, infrared sensors, thermistors, resistance temperature detectors (RTDs), or any other apparatus capable of detecting temperatures or changes in temperature. The temperature detecting element is preferably placed in proximity to the expandable member.

However, nowhere does the cited passage of Danek et al. appear to teach, suggest, or disclose a temperature sensing element disposed within the energy delivery device for monitoring temperatures created by use of the energy delivery device from within the energy delivery device, or the temperature detecting element coupled to a retractable member capable of moving independently of the energy delivery device. Hence, the cited passage cannot be considered as teaching, suggesting, disclosing “an optical sensor disposed within the cryo therapy apparatus for monitoring temperatures created by use of the cryo therapy apparatus from within the cryo therapy apparatus, the optical sensor coupled to a retractable member capable of moving independently of the cryo therapy apparatus”, as recited in claim 43. Accordingly, there appears to be no reason to modify Wittenberger et al. to have an optical sensor disposed within the cryo therapy apparatus for monitoring temperatures created by use of the cryo therapy apparatus from within the cryo therapy apparatus, the optical sensor coupled to a retractable member capable of moving independently of the cryo therapy apparatus. For at least these reasons, claim 43 is believed to be patentable over Wittenberger et al. in view of Danek et al. For similar and other reasons, claims 44, 46, and 49, which depend from claim 43 and include additional distinguishing features, are also believed to be

patentable over Wittenberger et al. in view of Danek et al. Withdrawal of the rejection is respectfully requested.

On page 3 of the Office Action, claims 52 and 64 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Wittenberger et al. in view of LePivert (U.S. Patent No. 6,551,309). Applicant respectfully traverses the rejection.

Claim 52 recites:

52. (Previously Presented) A device for minimally invasive medical treatment in a body of a patient, comprising:
a tubular member having a proximal end and a distal end;
a cryo therapy apparatus connected to the distal end of the tubular member and comprising a first balloon and a second balloon, the first and second balloons arranged to define an inner chamber and an outer chamber, at least a portion of the inner chamber being interior of the first balloon and at least a portion of the outer chamber being interior of the second balloon and exterior of the first balloon, a surface of the first balloon configured to retain a coolant within the inner chamber and a surface of the second balloon configured to retain the coolant within the cryo therapy apparatus if the first balloon fails and prevent loss of the coolant to the body of the patient; and
an optical imaging apparatus near the distal end of the tubular member to monitor temperatures resulting from use of the cryo therapy apparatus, wherein the cryo therapy apparatus is sized and arranged for vascular introduction.

Nothing in Wittenberger et al. or LePivert et al., taken either alone or in combination, appear to disclose many elements of claim 52, including for example, “a cryo therapy apparatus connected to the distal end of the tubular member and comprising a first balloon and a second balloon, the first and second balloons arranged to define an inner chamber and an outer chamber, at least a portion of the inner chamber being interior of the first balloon and at least a portion of the outer chamber being interior of the second balloon and exterior of the first balloon, a surface of the first balloon configured to retain a coolant within the inner chamber and a surface of the second balloon configured to retain the coolant within the cryo therapy apparatus if the first balloon fails and prevent loss of the coolant to the body of the patient” or “an optical imaging apparatus near the distal end of the tubular member to monitor temperatures resulting from use of the cryo therapy apparatus”.

In the Office Action, the Examiner appears to indicate that Wittenberger et al. fails to specifically disclose an optical imaging apparatus near the distal end of the tubular member to monitor temperatures resulting from use of the cryo therapy apparatus, but turns to LePivert for support. In particular, the Examiner cites CIS 17 of LePivert et al. as teaching the claimed optical imaging apparatus. Applicants respectfully disagree. LePivert et al. appears to disclose CIS 17 is a cryosurgical imaging system and column 4, lines 59-53 of LePivert et al. state “[a]n electrical line 16 connects the electrically conductive outer wall of the chamber, or electrical sensors of the the chamber, to the cryosurgical imaging system (CIS) 17 allowing the operator to monitor the freezing of tissues and the functioning of the probe”. Applicants respectfully submit that monitoring the “freezing of tissues” is clearly not the same as monitoring “temperatures resulting from use of the cryo therapy apparatus”, as in claim 52. Furthermore, as is clearly shown in Figure 1 of LePivert et al., CIS 17 does not appear to be near the distal end of the tubular member.

Additionally, the Examiner also cited to column 10, lines 34-51 of LePivert for support. The cited passages states:

In the one probe technique, the same probe fulfills the two requirements of hardening a thin layer of the tissue then treating it without moving the tip from its position. An embodiment of this technique consists in introducing a catheter 36, shown in FIG. 13, at the desired location through direct or imaging guidance, inserting the probe tip 15 into the catheter, introducing refrigerant into the probe while it remains with in the bore of the catheter to initially freeze the tissue while the catheter wall prevents the liquid/gas mixture from escaping. The catheter is then withdrawn, as in FIG. 13, a few millimeters or centimeters to let the gas/liquid mixture flow freely in contact with the tissue. The catheter inner diameter and the material are calculated to adapt to the tip size and to be moved smoothly when it is deemed necessary for the probe application. This technique allows shaping of the ice ball according to the numbers and location of openings exposed by the controlled withdrawal of external catheter.

As can be seen, nothing in the cited passage of LePivert appears to disclose the claimed optical imaging apparatus.

For at least these reasons, Applicants respectfully submit that LePivert cannot be considered as disclosing “an optical imaging apparatus near the distal end of the tubular member to monitor temperatures resulting from use of the cryo therapy apparatus”, as recited

in claim 52. For at least these reasons, claim 52 is believed to be patentable over Wittenberger et al. in view of LePivert et al. Withdrawal of the rejection is respectfully requested.

In the Office Action, the Examiner asserts that “the limitations of claim 64 are also recited in claim 52, thus is redundant”. This is not understood. Claim 64 recites “wherein the optical imaging apparatus detects temperatures resulting from use of the cryo therapy apparatus from within the cryo therapy apparatus”. Nowhere are such features provided in claim 52. As such, Applicants respectfully request that the Examiner either specifically address the features of claim 64 in a new Non-Final Office Action so that Applicants may have an opportunity to response, or indicate that the subject matter of claim 64 is allowable. Further, nowhere are such features taught or suggested in Wittenberger et al. or LePivert et al. For at least these reasons, claim 64, which depends from claim 52 and includes additional distinguishing features, is also believed to be patentable over Wittenberger et al. in view of LePivert et al.

Newly Presented Claims

With this Amendment, Applicants have added newly presented claims 65-73. For similar reasons discussed above, as well as others, claim 85-73 are also believed to be patentable over the cited references.

Conclusion

In view of the foregoing, all pending claims are believed to be in a condition for allowance. Further examination and withdrawal of the rejections is respectfully requested. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,
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By his Attorney,

Date: _____

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